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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
4141	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,485	BOCKOVICH ET AL.	
	Examiner	Art Unit	
	KAREN CHENG	4141	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,12-17,26 and 27* is/are pending in the application.

4a) Of the above claim(s) *15-17,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/1007, 4/11/2007, 5/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-10, 12-17 and 26-27 are currently pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

A national stage application, under 37 CFR 1.475(b), containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
(4) A process and an apparatus or means specially designed for carrying out said process; or
(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specially designed for carrying out said process.

Moreover, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case, the claims are drawn to multiple methods of use.

An election of a specific method of use is required: for example, a method of treating

A. hyperproliferative disorder (claims 12-14),

B. viral infection (claims 15-16),

C. alocepia (claim 17),

D. inhibiting cyclin-dependent kinase disorder (claims 26-27)

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the

inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election

During a telephone conversation with Applicant's Representative, Michael Wesolowski on 12/30/2010 a provisional election was made with traverse to prosecute the compound and its use in treating hyperproliferative disorder, claims 9-10 and 12-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-17 and 26-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

The application claims the benefit of priority to U.S. Provisional Application Nos. 60/531,872, filed on 12/23/2003, 60/560,138, filed on 04/06/2004 and 60/616,480, filed on 10/06/2004.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

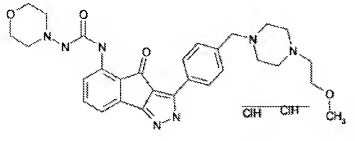
The abstract of the disclosure is objected to because it does not fully & specifically describe the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound



its prodrug, tautomeric, pharmacologically acceptable salt, N-oxide, or stereoisomeric form thereof, does not reasonably provide enablement for any "isomeric form" of said product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

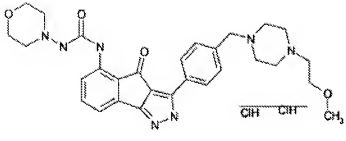
As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*. 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

In the instant case, the nature of the invention is the compound



, its prodrug, tautomeric, pharmacologically acceptable salt, N-oxide, stereoisomeric, or isomeric form thereof.

The state of the prior art and the predictability or lack thereof in the art

According to dictionary.com, an isomer is defined as "any of two or more compounds, radicals, or ions that contain the same number of atoms of the same elements but differ in structural arrangement and properties". The term isomer encompasses constitutional isomers – molecules that have the same molecular formula but atoms bonded together in different orders. For example, in the instant case, a compound having 4 oxygen atoms in a 6-membered ring rather than the 4 oxygen atoms that are part of a morpholine ring, carbonyl or ether group would still have the same number of oxygen atoms but differ in structural arrangement and could thus be considered an isomer.

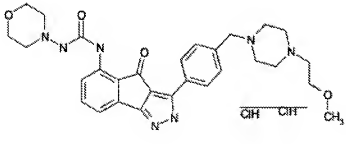
The amount of direction or guidance present and the presence or absence of working examples

The specification does not provide working examples in which an isomer (such as a constitutional isomer) of the compound is synthesized. Although p. 34 of the specification includes chiral, diastereomeric, racemic isomeric forms of the compound,

further direction as to other changes that could be made to the claimed compound are not given. Since there are various chemical moieties that could be encompassed by this term that are variable in reactivity, it cannot be said with absolute certainty such compounds could be prepared or exactly what compounds would fall under the broad definition of "isomer." There is no direction or guidance provided for ascertaining what chemical groups could be modified on the compound, and no guidance about synthetic routes to obtain such an "isomer." The generalized language for the definition of isomer does not convey the detailed identity of the invention, and what specific isomeric forms of the compound can be synthesized.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include the compound



, its prodrug, tautomeric, pharmacologically acceptable salt, N-oxide, stereoisomeric or isomeric form. The invention as claimed encompasses multiple derivatives of the compound having various functional groups and chemical reactivity. However the specification does not give provide specific examples of what can be considered an isomeric form of the compound.

The quantity or experimentation needed and the level of skill in the art

The level of difficulty required for the synthesis of functional isomers, including constitutional isomers is extremely high. The level of skill in pharmacology/organic chemistry is also very high. However, despite such a high level of skill in the requisite art, the creation of isomers is unpredictable to the extent that undue experimentation is required in order to make and use isomers of the claimed compound. There is an insufficient showing in the Specification, or the state of the art does not acknowledge that the isomers of the claimed compound can be created via routine experimentation. Additionally, it would require undue experimentation of one of ordinary skill in the art to ascertain what could be considered an "isomer." Factors such as "sufficient working examples", "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant compound claim. One would need to prepare compounds with similar structural radicals and/or biological activity without any direction as to what compound(s) could be considered an isomer or how different the isomer can be from the compound. In view of the breadth of the claims, the chemical nature of the invention and the lack of working examples regarding the process as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

In consideration of each of the Wands factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Therefore; claims 9 and 12-14 are rejected under 35 U.S.C. § 112, 1st paragraph. These rejections could be overcome by deleting the phrases "isomeric" from the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*. 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

"Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." MPEP 2163(II)(1), citing In re Morris,127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Accordingly the scope of diseases claimed to be treated would be all types of cancerous tumors, ranging from breast cancer, prostate cancer, lung cancer, etc. Given the scope of the many types of cancerous tumors included within claims 13-14, their varied etiologies, and the diversity of their patient populations, the disclosure in the Specification is insufficient to permit a person skilled in the art to employ a compound "treating all cancers."

The nature of the invention

The nature of the invention is directed toward a method of treating a hyperproliferative disorder or inhibiting proliferation of a cell comprising administering the claimed compound or contacting a cell with the claimed compound.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat diseases a hyperproliferative disorder, such as cancer). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that that contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any preventive regimen on its fact.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427

F.2d833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants' claims include the treatment disease processes such as hyperproliferative diseases, including any cancer (see p. 49 of specification). The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types and that cancer classification has been based primarily on morphological appearance of the tumor. Tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub *et al*, page 531).

According to information from the National Cancer Institute, targeted cancer therapies, which are defined as drugs or other substances that block the growth and spread of cancer by interfering with specific molecules involved in tumor growth and progression, requires identification of good targets. Targeted therapies are specific for a type of cancer (ie non-small cell lung cancer or peripheral T-cell lymphoma). Out of the many types of drug compounds, only several are even being studied in clinical trials for treating a specific types of cancer. Due to the unpredictable nature of cancer and the fact that over 3,000 different cancers exist, the various types of cancers have different causative agents, involve different cellular mechanisms, and differ in treatment protocol, thus no single compound exists presently that is known to treat *all* cancers as

a blanket therapeutic. It also has not been established that antiproliferative activity would be an effective treatment for all types of cancerous tumors.

The amount of direction or guidance present and the presence or absence of working examples

The specification describes assays that measure the effectiveness of test compound(s) on the proliferation of human cells. The compounds are shown to be inhibitors of cyclin-dependent kinases (cdk) enzymes and concentrations of the compounds needed to suppress 50% of cell proliferation (IC_{50} values) (see p. 81-88). Though cdk inhibitors may be effective for inhibiting angiogenesis, this only suggests that compound could be effective for inhibiting the growth of only certain *specific* type of solid tumors.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include the treatment of hyperproliferative disorder(s), but the specification only provides evidence for the effect the compounds have on enzymes that have been shown to play a roll in cell division. However no test results disclosing the actual effect of the compounds on subjects that show evidence of any disease has been shown. It is known that promising *in vitro* results do not necessarily translate to successful treatments when administered *in vivo*.

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain the effectiveness of the compound in the treatment and prevention of cancer.

Factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. Cancer treatment depends on the different causative agents and cellular mechanisms involved in each type of cancer. Consequently, different treatment protocols are required, depending on the type of cancer present. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of treating cancer, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

Genentech Inc. v. Novo Nordisk NS (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, it is apparent that undue experimentation is necessary because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Therefore, claims 13-14 are rejected under 35 U.S.C. § 112, 1st paragraph.

Claim Rejections - 35 USC § 103

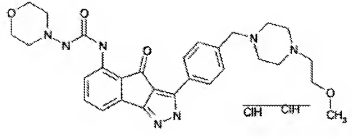
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

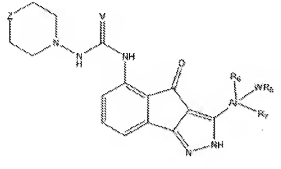
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

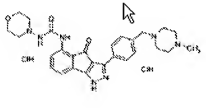
Claims 9-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker *et al* (see US Pat Pub No. 2004/0266854, which claims priority to US Provisional Application 60/460,921 filed on Apr. 7, 2003) and Nugiel *et al* (see US Patent No. 6,407,103) in view of Lima *et al* (Current Medicinal Chemistry 2005, 12, p. 23-49) .

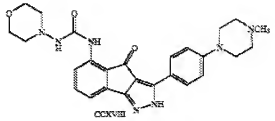
Applicants' instant elected invention in claims 9-10, 12-14 teaches the compound  , its pharmaceutical composition and method of use.

Determination of the scope and content of the prior art (MPEP §2141.01)

Becker *et al* disclose compounds of formula II



wherein Z represents O, V represents O, Ar represents a phenyl ring, W represents CH_2, R_5 represents M_nQ where n=0 and Q is a substituted nitrogen-containing heteroaryl ring, such as piperazine, R_6 and R_7 represent H, specifically compound A49  (p. 83 of specification of 06/460,921).

Nugiel *et al* disclose compound  (see column 89).

Lima *et al* teach that similarities in physicochemical properties allow substitution of certain atoms to elicit similar biological activity and allow for the rational modification of compounds. Bioisosterism is considered to be a strategy of Medicinal Chemistry for rational design of new drugs. On p. 25, Table 1, an –OR and -CH_3 group are considered to be classic bioisosteres.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Becker *et al* and the instantly claimed compound of applicant is that the invention of Becker *et al* are directed to compounds wherein there is N-alkyl substituted piperazine ring rather than the N-alkyl-methoxy substituted piperazine ring found in the instant invention.

The difference between the prior art of Nugiel *et al* and the instantly claimed compound of applicant is that the invention of Nugiel *et al* are directed to compounds wherein there is N-alkyl substituted piperazine ring rather than the N-alkyl-methoxy substituted piperazine ring found in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Becker *et al* in view of Lima *et al* are analogous art because all the compounds possess similar activity. The compounds of Becker *et al* show cdk inhibiting activity and

can be used in development of drugs with biological activity. The teaching of Lima *et al* shows that substitution of CH_3 by OR is a bioisosteric replacement, and bioisosteric substitution can be used for rational design of new drugs. It is common for one skilled in the art to synthesize structurally related compounds in hopes of obtaining greater activity on the desired target. This is commonly known as structure-activity relationship (SAR) in the chemical arts. In the absence of unexpected results, one skilled in the art would expect that the instant claims which are analogous to the compound of Becker *et al* in view of Lima *et al*. The motivation to make the claimed compound(s) derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In the instant case, substitution of a methyl group for an ether group would have been desirable in order to find compounds that posses greater activity as cdk inhibitors. The explicit teaching of Becker *et al* in view of Lima *et al* together with the enabled examples would have motivated one skilled in the art to modify the known compounds with such generic teaching with the expectation that they would all have similar utility.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

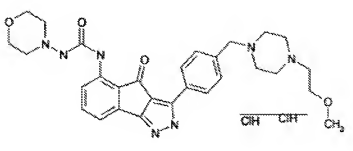
from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

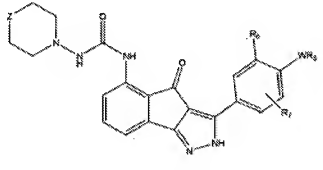
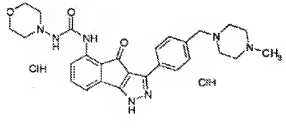
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 9, 10 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 10 and 15 of Patent No. 12/456,539, notice of issue dated 10/12/2010. Although the conflicting claims are not

identical, they are not patentably distinct from each other because applicants are claiming compound  and its pharmaceutical composition.

Conflicting claims 1, 4, 6, 10 and 14-15 of Patent No. 12/456,539 are drawn to compounds of Formula  wherein Z represents O, W represents CH_2, R_5 represents M_nQ, R_6 represents H, R_7 represents H, n represents an integer 0 when present in R_5 and Q represents a substituted nitrogen-containing heterocycle, such as a compound found in claim 14  .

The difference between the claims at issue and the conflicting claims is found in the scope of the claims. The instant claims are drawn to a more specific compound that is embraced within the scope of the conflicting claims of application 12/456,539.

It would have been obvious to one of ordinary skill in the art, when faced with the conflicting claims of Patent No. 12/456,539 to synthesize applicants' instantly claimed compound to inhibit cyclin-dependant kinase (cdk) since compounds of similar scope had been found to have the same activity. The motivation would be the expectation of success in use of applicants' compounds as cdk inhibitors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN CHENG whose telephone number is (571)270-7381. The examiner can normally be reached on M-F, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

Karen Cheng
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